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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/566,411	RINALDI ET AL.
Office Action Summary	Examiner	Art Unit
	Nathan W. Schlientz	1616
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of the Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 21 Ja 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowal closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	
Disposition of Claims		
 4) Claim(s) 1-13 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) 1-13 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o 	wn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the I drawing(s) be held in abeyance. See iion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list 	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ☐ Interview Summary Paper No(s)/Mail Da 5) ☐ Notice of Informal F	ate
Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	6) Other:	альн, фриманон

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 January 2010 has been entered.

Status of the Claims

Claims 1-13 are pending in the present application and are thus examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

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Specification

It is noted that the amendment to the specification filed 3 April 2009, and instant claims 6 and 10 comprise amounts of zinc, copper, manganese and selenium that do not correlate with the examples. For instance, Example 1 of the specification comprises 37.5 mg zinc, 12 mg copper, 22.5 mg manganese and 13.75 mg selenium; whereas instant claims 6 and 10 comprise 7.5 mg zinc, 1.25 mg copper, 2.25 mg manganese and 0.03 mg selenium, and the amendment to the specification comprises 7.5 mg zinc and 1.25 mg copper. Example 1, claims 6 and 10, and the amendment to the specification comprise the same amounts of methyl sulfonyl methane, spermidine trihydrochloride, vitamin C, vitamin E, vitamin B6, calcium d-pantothenate and d-biotin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Raisfeld (US 4,507,321).

Raisfeld discloses topical or oral compositions comprising a polyamine, such as spermine or spermidine, which are useful to regulate, i.e., stimulate or inhibit, epithelial cell growth (Abstract; col. 2, ln. 68; col. 3, ln. 1, 27-33 and 58-68; and col. 3, ln. 1-19). Raisfeld further discloses examples wherein topical or oral formulations comprise spermine or spermidine (Examples 1, 2 and 4-11). See also claims 1, 2, 5, 8, 9, 13 and 14.

Response to Arguments

Applicants argue on page 6 that a method of cosmetic treatment to improve hydration of the skin to maintain beauty is not made known or obvious by prior art describing a therapeutical treatment of pathological or damaged skin based on cell renewal or possibly even cell inhibition. Applicants argue that none of the cited documents describe or suggest that spermine and/or spermidine in free or salified form can be active as cosmetics inasmuch as they are able to withhold water at the stratum corneum of the epidermis, so that they can improve hydration of the human skin to maintain beauty in any subject. In contrast, all of the cited prior art documents relate to the treatment of skin of a subject suffering from a pathological disorder or having damaged skin for cell regeneration processes in pathological or damaged skin.

However, the examiner respectfully argues that instant claims 1 and 2 are drawn to a method of cosmetically treating human skin by topically or orally administering spermine and/or spermidine to improve hydration and maintain beauty of the skin.

Therefore, topically or orally administering spermine and/or spermidine to human skin will inherently improve hydration and maintain beauty of the skin. Raisfeld teaches topically or orally administering spermine and/or spermidine to human skin. Thus, in the absence of evidence to the contrary, administration of spermine and/or spermidine according to Raisfeld inherently improves hydration and maintains beauty of the skin.

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The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Also, claims 3, 4, 7, 8, 11 and 12 are drawn to a composition wherein the intended use is to administer said composition to humans. However, the recitation of the intended use "for administration in humans with a restriction to improve hydration and maintain beauty of human skin and skin appendages" has not been given patentable weight to distinguish over Raisfeld because the intended use of the claimed invention must result in a structural difference between the claimed invention and the

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Raisfeld discloses compounds that are the same as those claimed, they would be capable of performing the intended use, as claimed.

Applicants also argue that it should be pointed out that claim 6, which refers to the main composition claim 3, describes a range of 0.25-0.5 mg of spermidine trihydrochloride, which - by calculation - corresponds to approximately 0.02-0.04 % of free spermidine in an oral administration unit (such as the tablets of the examples). Example 10 of Raisfeld describes a capsule with 50 mg of spermidine, which amounts to 16.6% b.w. of that capsule. However, the examiner respectfully argues that claim 6 is not included in the rejection above.

It is noted that Applicants stated on page 7 that claim 3 corresponds to approximately 0.02 to 0.04 wt.% free spermidine. However, it is believed by the examiner that Applicants are taking into consideration the amount of microcrystalline cellulose, calcium phosphate dibasic dihydrate, HPMC, magnesium stearate and silicon dioxide, as well as the increased amounts of zinc, copper, manganese and selenium recited in Example 1. As instantly claimed, claim 3 does not comprise microcrystalline cellulose, calcium phosphate dibasic dihydrate, HPMC, magnesium stearate and silicon dioxide and comprises lower amounts of zinc, copper, manganese and selenium than recited in Example 1. Thus, the amount of spermidine trihydrochloride in claim 3 is

approximately 0.07 to 0.16 wt.% corresponding to approximately 0.04 to 0.10 wt.% free spermidine.

2. Claims 1-4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Charonis et al. (WO 94/12464).

Charonis et al. disclose polyamines which are useful for treating tissue aging (Abstract), wherein the composition is suitable for topical or oral administration (pg. 11, ln. 20-22), and the preferred polyamines include spermine and spermidine (claims 1 and 4-8).

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

3. Claims 1-4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ilenchuk et al. (WO 99/51213).

Ilenchuk et al. disclose the topical administration of polyamines in the palliative treatment of chronic diseases and disorders of epithelial tissue, such as dry skin and Winter itch (Abstract). Ilenchuk et al. disclose that the use of polyamines for therapeutic treatment of tissue damage is known (pg. 12, ln. 33-35), wherein it is taught that polyamines regulate, stimulate or inhibit epithelial growth (pg. 13, ln. 1-11). Ilenchuk et al. further disclose that the preferred polyamines include spermidine and spermine in the free base form or acid addition salt form (pg. 19, ln. 20, 21; and pg. 20, ln. 15-18),

and the compositions are suitable for topical and oral administration (pg. 20, ln. 25-35) for the treatment of dry skin and Winter itch (i.e., improve hydration) (pg. 14, ln. 6 and 25; and pg. 18, ln. 24). Ilenchuk et al. disclose several examples wherein spermine or spermidine is formulated into topical or oral administration formulations (pg. 22-27, Preparations 1-11). See also claims 1-8.

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

4. Claims 1-4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckart et al. (EP 0 884 046 A1).

Eckart et al. disclose cosmetic compositions with photoprotective properties, wherein the compositions comprise Vitamin E, Vitamin C, and at least one natural polyamine (Abstract). Eckart et al. disclose that especially preferred natural polyamines are spermine and spermidine (col. 2, ln. 13-14); and that the compositions are formulated as cosmetic skin-care products (col. 4, ln. 42-44). Eckart et al. disclose that free oxygen radicals in the skin, which result from UV exposure, attack skin constituents that are responsible for retention of elasticity and or moisture in the skin (col. 1, ln. 7-12). Eckart et al. state that in order to provide a protection of the skin against the formation of these free radicals, skin-care compositions are provided on the skin which contain anti-oxidants that may penetrate the skin and act as radical scavengers (col. 1, ln. 22-26). Among the most effective radical scavengers are the Vitamin C and Vitamin

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E based derivatives (col. 1, In. 27-28), and the polyamines (i.e., spermine and spermidine) in combination with Vitamin E and C based derivatives show a synergistic improvement in effectivity. Eckart et al. disclose an example wherein a sun protection balm was prepared comprising D-panthenol, Vitamin C, spermine, and tocopherol (Example 2). See also claims 1, 8 and 11.

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Response to Arguments

Applicants argue on page 7 that Eckart shows how to enhance the photo protective activity of the active principles vitamins C and E on the skin irradiated with UV. Polyamines are only enhancers. Accordingly, the hydration improvement on nonirradiated skin resulting from the clinical study in the present application is therefore a different effect. However, the examiner respectfully argues that the claims do not limit the skin to that which has not been exposed to UV irradiation. Also, the skin as disclosed in Eckart et al. is not damaged by the UV irradiation, but rather the composition prevents damage from the UV irradiation. Furthermore, Eckart et al. disclose that the free oxygen radicals in the skin, which result from UV exposure, attack skin constituents that are responsible for retention of elasticity and or moisture in the skin. The compositions according to Eckart et al. provide a protection to the skin against the formation of these free radicals through incorporation of anti-oxidants that act as radical scavengers. The polyamines (i.e., spermine and spermidine) in combination with Vitamin E and C show a synergistic improvement in effectivity. Therefore, the compositions of Eckart et al. improve moisture in the skin by preventing attack on the constituents of the skin that are responsible for moisture in the skin. Also,

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as discussed above, claims 3-12 are drawn to the composition and its intended use in

not given patentable weight to distinguish over Eckart et al.

5. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated

by Wolf et al. (WO 98/06376).

Wolf et al. disclose a nail strengthening composition comprising tocopherol,

pantetheine, pyridoxine, biotin and spermine (Example 1; and claims 18-20). It is noted

that Applicants define skin appendage in the instant specification as including nails (pg.

1, In. 31).

Response to Arguments

Applicants do not specifically argue the rejection with respect to Wolf et al.

Therefore, the compositions according to claims 3, 4, 8 and 12 are anticipated for the

reasons discussed above.

6. Claims 1-4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by

Hahn et al. (WO 96/23490).

Hahn et al. disclose compositions and formulations containing polyamines for

inhibiting skin irritation in animals (Abstract). Hahn et al. further disclose that the

composition is for topical administration and comprises spermine or spermidine (claims

1 and 2).

Response to Arguments

Applicants argue that Hahn does not relate to cosmetic treatment of human skin, rather it relates to animals for inhibiting skin irritation. Hahn et al. clearly teach administering their compositions to human skin (claims 14-17). Also, it is noted that Hahn et al. disclose the use of their composition as a cosmetic product (claim 18), wherein the cosmetic product is a cream, lotion or *moisturizer* (claim 44). Therefore, the compositions according to Hahn et al. would inherently result in improvement of hydration and beauty of the skin, as discussed above.

7. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara et al. (JP 2003/113047 A).

Matsubara et al. disclose a hair cosmetic preferably comprising spermine or spermidine (Abstract). It is noted that Applicants define skin appendage in the instant specification as including hair (pg. 1, ln. 31).

Response to Arguments

Applicants do not specifically argue the rejection with respect to Wolf et al. Therefore, the compositions according to claims 3, 4, 8 and 12 are anticipated for the reasons discussed above.

8. Claims 3, 4, 7, 8 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoshima et al. (JP 07/268323 A).

Minoshima et al. disclose a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol and ascorbic acid (Abstract). The amount of

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spermine or spermidine is preferably 0.01-70 wt.% (Abstract). Minoshima et al. disclose an example wherein the composition comprises 200 ppm spermine (0.02 wt.%) ([0025]).

Response to Arguments

Claims 3, 4, 7, 8 and 11-13 are drawn to compositions and as such their intended use is not given patentable weight to distinguish over Minoshima et al., as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 1. Claims 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoshima et al. (JP 07/268323 A) in view of Henderson (WO 00/37087), Ioannides (WO 02/15860) and Eckart et al. (EP 0 884 046 A1).

Determination of the scope and content of the prior art (MPEP 2141.01)

Minoshima et al. teach a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol (Vitamin E) and ascorbic acid (Vitamin C) (Abstract).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Minoshima et al. do not teach the composition further comprising methyl sulfonyl methane, Vitamin B6, calcium d-pantothenate, biotin, zinc, copper and manganese amino acid chelates, and selenium, as instantly claimed. However, Henderson teaches that amino acid chelates of copper, zinc and manganese, and optionally selenium are known to reduce free radical cellular oxidative stress by strengthening and maintaining the activities of enzymes known to remove harmful superoxides, peroxides, and hydroxides (pg. 8, In. 24-27). Henderson teaches that proper metabolic functioning of minerals such as copper, zinc and manganese in addition to or independent of selenium play an important role in maintaining the function of oxidative enzymes that relate to oxidative bursts in neutrophils and macrophages, and in controlling or alleviating free radical cellular oxidative toxicity (pg. 10, In. 11-20). Henderson further teaches that vitamins are essential for maintaining good health (pg. 11, ln. 19), and vitamins C, E, B6, biotin and pantothenic acid are advantageously added to a comprehensive dietary supplement; wherein Vitamins C and E also provide antioxidant function (pg. 12, ln. 12-32). Henderson teaches that the preferred amount in parts by weight of zinc is 1-25 x 10^{-3} , selenium is 1-75 x 10^{-6} , copper is 0.1-2 x 10^{-3} , manganese is 0.1-10 x 10^{-3} , Vitamin C is 10-500 x 10^{-3} , Vitamin E is 1-500 IU, Vitamin B6 is 0.1-20 x 10^{-3} , biotin is 25-200,000 x 10^{-6} , and pantothenic acid is 1-50 x 10^{-3} (pg. 11, ln. 1-14; and pg. 12, ln. 15-28).

Eckart et al. teach that the free oxygen radicals in the skin, which result from UV exposure, attack skin constituents that are responsible for retention of elasticity and or moisture in the skin. The compositions according to Eckart et al. provide a protection to the skin against the formation of these free radicals through incorporation of anti-oxidants that act as radical scavengers. The polyamines (i.e., spermine and spermidine) in combination with Vitamin E and C show a synergistic improvement in effectivity. Therefore, the compositions of Eckart et al. improve moisture in the skin by preventing attack on the constituents of the skin that are responsible for moisture in the skin.

Minoshima et al. do not teach the addition of methylsulfonylmethane to their pharmaceutical compositions. However, loannides teaches that methylsulfonylmethane (MSM) is added to ascorbic acid as an anti-inflammatory and to accelerate healing (pg. 25, ln. 13-16).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add vitamins and minerals to the formulations of Minoshima et al. to enhance the anti-oxidative properties and improve overall health, as

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reasonably taught by Henderson and to improve skin hydration as reasonably taught by Eckart et al.; as well as adding methylsulfonylmethane as an anti-inflammatory agent to accelerate healing, as reasonably taught by loannides.

With respect to the amounts of each component listed in instant claims 6 and 10, the examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

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Applicants argue on pages 9-10 that the declaration shows that it was unexpected that spermidine and/or spermine could hold water at the stratum corneum of the epidermis in non-pathological or non-aged conditions. However, the examiner respectfully argues that claims 5, 6, 9 and 10 are drawn to compositions and the intended use is not given patentable weight to distinguish over Minoshima et al. in view of Henderson and Ioannides. Also, Eckart et al. teach that polyamines, such as spermine and spermidine, in combination with Vitamin C and E show a synergistic improvement in scavenging the free oxygen radicals in the skin that attack the constituents of the skin that are responsible for retention of elasticity and of moisture in the skin. Thus, Eckart et al. teach that spermine or spermidine in combination with Vitamins E and C will improve skin hydration by scavenging the free radicals that attack the skin constituents responsible for moisture in the skin.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NWS

/Johann R. Richter/ Supervisory Patent Examiner, Art Unit 1616